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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE STATE OF CALIFORNIA; THE STATE OF DELAWARE; THE STATE OF MARYLAND; THE STATE OF NEW YORK; THE COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v.

ERIC D. HARGAN, in His Official Capacity as Acting Secretary of the U.S. Department of Health & Human Services; U.S. DEPARTMENT OF HEALTH HUMAN SERVICES; R. ALEXANDER ACOSTA, In His Official Capacity as Secretary of the U.S. DEPARTMENT OF LABOR; STEVEN MNUCHIN, In His Official Capacity as Secretary of the U.S. DEPARTMENT OF THE TREASURY; U.S. DEPARTMENT OF THE TREASURY; DOES 1-100,

Defendants.

4:17-cv-05783-HSG

STATES' REPLY IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

Date:	Dec. 12, 2017
Time:	2:00 p.m.
Dept:	2, 4th Floor
Judge:	Hon. Haywood S. Gilliam, Jr.
Trial Date:	Not set
Action Filed:	October 6, 2017

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

STATUTES

TABLE OF AUTHORITIES
(continued)

Page

OTHER AUTHORITIES

CONGRESSIONAL RECORDS

INTRODUCTION

Women across the nation must continue to have access to the no-cost contraceptive guaranteed under the Patient Protection and Affordable Care Act (ACA). Defendants' interim final rules (IFRs) make this important benefit optional. Defendants' characterization of this case as about "religious liberty and freedom of conscience," ECF No. 51 at 1, mirrors the IFRs themselves, which disregard the very law they should implement.

Congress made women's access to affordable preventive care a priority when it enacted the Women's Health Amendment to ensure that health plans cover women's "preventive care and screenings" without "impos[ing] any cost sharing." 42 U.S.C. § 300gg-13(a)(4). Contraception and family planning were to be central to the preventive services covered in improving public health and lowering health costs for women.[1] Later, Congress considered but declined to include a "conscience amendment" to permit employers and insurers to deny coverage based on "religious beliefs or moral convictions." 158 Cong. Rec. S539 (Feb. 9, 2012) (S. Amdt. 1520, Section (b)(1), 112th Congress (2011-2012)). But employers with sincere religious objections were expressly acknowledged through a carefully tailored exemption and accommodation to relieve such employers from the obligation to provide contraceptive coverage. The States seek to maintain this religious protection.

In contrast, rather than continuing to allow for *both* contraceptive access—a public health imperative—and sincere religious objections, Defendants rushed into effect, without notice or public comment, two IFRs—one with an exceedingly broad religious exemption and another, novel exemption for *moral* objections. This about-face in policy effectively nullifies the ACA guarantee that, since 2012, has afforded women equal access to preventive medical care, including access to contraceptives, sterilization, and related patient education, counseling, and doctor's office visits. ECF No. 24-1 at 8. Defendants purport to "bring to a close" litigation brought by religious objectors, *id.* at 33, yet the IFRs run afoul of the Supreme Court's directive in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), not only to "accommodate[] petitioners' religious

[1] *See, e.g.*, 155 Cong. Rec. S12,033, S12,052 (Sen. Franken) ("health reform includes . . . access to affordable family planning services . . . Access to contraception is fundamental").

exercise," but also to "ensur[e] that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." *Id.* at 1560 (quotations omitted).

Defendants' urgency in implementing the IFRs circumvents the Administrative Procedure Act's (APA) normal rule-making process without adequate legal justification.[2] And in undermining the ACA, rather than faithfully implementing it, the IFRs further violate the APA because they exceed statutory authority and are arbitrary and capricious. The IFRs are also unconstitutional; in discriminating against women, they violate the Establishment Clause and Equal Protection Clause. The public interest would be served by a nationwide injunction maintaining the status quo that existed before the IFRs were issued.

ARGUMENT

I. THE STATES ARE LIKELY TO SUCCEED ON THE MERITS

A. The Northern District of California Is the Proper Venue for This Lawsuit

A civil action against an officer of a United States agency in his official capacity may be brought in any judicial district in which "the *plaintiff resides* if no real property is involved in the action." 28 U.S.C. § 1391(e)(1)(C) (emphasis added). Here, the plaintiff is the state, which "is held to reside in any district within it." 14D Wright & Miller, *Fed. Prac. & Proc.* § 3815 (4th ed. 2017) (citing *Ala. v. Army Corps of Eng'rs*, 382 F. Supp. 2d 1301, 1327-29 (N.D. Ala. 2005) (in action by state against federal government, the state "resided," and venue was proper, in any district within the state). As no real property is involved here, venue is proper in this Court.

B. The States' APA Claims Are Likely to Succeed

1. The States Have Standing to Bring APA Claims

The States have "a sufficiently personal stake in the outcome of the controversy to ensure that the parties will be truly adverse and their legal presentations sharpened." *Washington v. Trump*, 847 F.3d 1151, 1159 (9th Cir. 2017) (quotations omitted) (citing *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007)). To establish standing, the States, like any other party, must demonstrate that (1) they have suffered an "injury in fact," (2) there exists a "causal connection"

[2] This urgency—and Little Sisters of the Poor's eagerness to contest this lawsuit—also suggest that religious objectors are likely to avail themselves of the new exemptions, causing women to lose contraceptive coverage and strengthening the States' standing as affected parties.

between the injury and the challenged conduct, and (3) a favorable judicial ruling will "likely" redress the injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

In bringing APA claims, the States are asserting a "procedural injury," which requires a showing that (1) the federal agency violated certain procedural rules, (2) these rules protect the States' concrete interests, and (3) it is reasonably probable that the challenged action will threaten the States' concrete interests. *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 969-70 (9th Cir. 2003). Importantly, the States can establish standing for a procedural injury under the APA "without meeting all the normal standards for redressability and immediacy." *Hall v. Norton*, 266 F.3d 969, 975 (9th Cir. 2001) (quoting *Lujan*, 504 U.S. at 572 & n.7).

The States satisfy these three criteria for standing. First, Defendants violated the APA by issuing, without notice and prior opportunity for comment, IFRs that are not in accordance with law, exceed statutory authority, and are arbitrary and capricious. Second, these procedural rules requiring notice and comment protect the States' concrete interest in ensuring that women have access to no-cost contraceptive coverage. This interest of the States is "congruent" with that of their women residents, *City of Sausalito v. O'Neill*, 386 F.3d 1186, 1197 (9th Cir. 2004); the IFRs create a barrier to contraceptive access that burdens the States with increased costs of providing contraceptive services to eligible residents and of funding medical procedures and other expenses associated with unintended pregnancies. *See, e.g.*, Decl. of Lawrence Finer [Finer Decl.] ¶¶ 54, 61, 69, 77, 85, 93; Decl. of Massey Whorley [Whorley Decl.] ¶¶ 8, 10, 11; Decl. of Mari Cantwell [Cantwell Decl.] ¶ 17; Decl. of Jenna Tosh [Tosh Decl.] ¶¶ 26-28, 34; Decl. of Karen Nelson [Nelson Decl.] ¶ 15; Decl. of Karyl Rattay [Rattay Decl.] ¶¶ 5, 7, 8.[3] Third, given that both IFRs apply immediately, ECF Nos. 24-1 at 1, 24-2 at 1, and as Defendants concede, allow employers not bound by state contraceptive equity laws to claim an exemption or accommodation, ECF No. 51 at 9-10, the IFRs will threaten this concrete interest.[4] Indeed, even

[3] Defendants argue that the Court should not consider declarations and should rely only on the administrative record. ECF No. 51 at 27. Yet the record is clearly inadequate—it ends in 2016, before any public comment on these IFRs— and the States also raise constitutional claims.

[4] Defendants suggest that the contraceptive equity laws in California, Delaware, Maryland, and New York, which required insurance plans that cover prescription drugs to also

under the IFRs' conservative estimates, tens of thousands of women will lose contraceptive coverage under the new regime. ECF Nos. 24-1 at 24-33, 24-2 at 19-21. Because enjoining the IFRs would redress the States' procedural injuries, the States have standing.[5]

2. The IFRs Are Invalid Under the APA Because They Are Not in Accordance with the Law and Exceed Statutory Authority

a. The IFRs Are Contrary to Law Because They Violate the ACA

Defendants contend that Congress delegated to them complete authority to determine the scope of required women's health coverage under the ACA, and even whether to provide contraceptive coverage at all. ECF No. 51 at 3, 20-21. But the plain language of the ACA insists that "preventive care" with respect to women "shall" be provided. 42 U.S.C. § 300gg-13(a)(4).

Defendants claim that because the guidelines implementing the Women's Health Amendment were not yet drafted at the time the ACA was passed, Congress irrevocably delegated unfettered authority to Defendants. ECF No. 51 at 20. Defendants acknowledge that the other three categories of services that must receive coverage without cost-sharing (42 U.S.C. § 300gg-13(a)(1)-(3)) are limited by the scope of the applicable guidelines. Defendants further recognize that subdivision (a)(3), which provides for children's services, and subdivision (a)(4), which provides for women's services, have nearly the same language. Children must receive the services "provided by" HRSA, whereas women must receive the services "as provided by" HRSA. Those two phrases have no difference in meaning and the scope of the covered services in both subdivisions should be equally bound by the content of the respective guidelines. In an argument not asserted in the IFRs themselves, Defendants contend that "the use of the word 'as'

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cover contraceptives, are alone enough to ensure that women will not lose contraceptive coverage under the IFRs. ECF No. 51 at 9-10. Yet Defendants acknowledge that Virginia does not have a contraceptive equity law. *Id.* Additionally, Delaware does not require cost-fee coverage. ECF No. 24 at 16. And Defendants neglect to mention that these laws do not apply to self-insured plans, which are governed by the Employee Retirement Income Security Act (ERISA). *See* 29 U.S.C. §§ 1144(a), (b)(2)(A). Self-insured plans cover 3 in 5 U.S. workers with employer-sponsored insurance and are governed exclusively by the federal government. Kaiser Family Foundation, *Employer Health Benefits 2017 Annual Survey*, at 164, *available at* http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.

[5] The States also have nonconstitutional standing to bring APA claims: under section 10(a) of the APA, "any 'person . . . adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial relief thereof.'" *City of Sausalito*, 386 F.3d at 1200 (quoting 5 U.S.C. § 702). A "person" includes the States. 5 U.S.C. § 551(2).

reinforces Congress's delegation to HRSA to determine . . . the manner and reach of that coverage," ECF No. 51 at 20, but Defendants provide no reasoning for the weight they attach to that single word. The fact that the guidelines were not drafted when the ACA was enacted does not allow Defendants to avoid or ignore the scope of coverage those guidelines now require.

To the contrary, the ACA expressly forbids a regulation that "creates any unreasonable barriers" to medical care, "impedes timely access to health care services," or discriminates based on sex. 42 U.S.C. §§ 18114, 18116. The IFRs constitute such unreasonable barriers for women. Broadly, the ACA sought to ensure universal access to quality, affordable health coverage. More specifically, the ACA sought to reduce gender disparities in health for women by requiring coverage of reproductive health care, maternity care, and other services that only women require, while also reforming the way insurance companies charge women for health care. Congress determined that preventive services are critical to improving public health outcomes and, relatedly, social and economic status for women. Thus, Congress included a specific provision for women's health services to remedy the problem that women were paying significantly more out-of-pocket for preventive care and thus often failed to seek critical preventive services. *Priests for Life v. HHS*, 772 F.3d 229, 235 (D.C. Cir. 2014); *Burwell v. Hobby Lobby*, 134 S. Ct. 2751, 2785-2786 (2014) (Kennedy, J., concurring).

"Extensive empirical evidence demonstrates what common sense would predict: eliminating costs leads to more effective and continuous use of contraception," and using contraception is a necessary part of women's health care. Finer Decl. ¶ 25. The inclusion of women's preventive services as a core part of the ACA's essential health benefits requirement, 42 U.S.C. § 18022, was critical to fulfilling Congress's goals of ensuring complete coverage of preventive care, better health outcomes for women, and an end to discrimination against women in health care. The IFRs increase the impediment to contraceptive access, and that, "in turn, will increase those women's risk of unintended pregnancy and interfere with their ability to plan and space wanted pregnancies. These barriers could therefore have considerable negative health, social and economic impacts for those women and their families." Finer Decl. ¶ 38. In short,

enacting IFRs that eliminate cost-free contraceptive coverage do precisely what the ACA forbids: create barriers between women and access to no-cost preventive care.

Defendants point to the exception for grandfathered plans as evidence that Congress did not universally require preventive services, as if the grandfathering suggests that those services were less important. ECF No. 51 at 21. But this exception allowed for gradual implementation of the ACA mandates, not complete avoidance. Defendants cite no authority showing Congressional intent to weaken the mandated coverage for preventive care. To the contrary, the specificity of this narrow exception shows that Congress intended a broad reach of the ACA mandated benefits.

b. The Religious Freedom and Restoration Act Does Not Require Defendants to Promulgate a Rule that Prevents Women from Accessing Their Statutorily-Entitled Benefits

Defendants claim that the Religious Freedom and Restoration Act of 1993 (RFRA) requires the Religious IFR, but they concede it cannot support the Moral IFR. ECF No. 51 at 25. Under RFRA, if the government substantially burdens the exercise of religion, then the burden must be in furtherance of a compelling interest and the least restrictive means of furthering that interest. 42 U.S.C. § 2000bb-1(b). Thus, RFRA requires the agency to find narrowly tailored solutions to provide for compelling governmental interests without trampling on religious freedom.

No court has ever required, or even considered, a religious exemption of the IFRs' breadth. *Hobby Lobby* was limited to closely-held for-profit corporations and *Zubik* was limited to non-profits. But the IFRs extend the exemptions to publicly-traded, for-profit corporations. Further, as Defendants concede, *Zubik* left open the question of whether the self-certification process was a "substantial burden on the exercise of religion." ECF No. 51 at 6-7. Before *Zubik*, nine courts had considered this question, and eight of them had concluded that there was no RFRA violation. *Zubik* simply allowed Defendants to consider a compromise, but in no way did it require that the accommodation become optional and the exemption be extended to for-profit corporations, insurers, and individuals—entities that were not even party to the *Zubik* litigation. [6]

[6] The States do not concede that the contraceptive coverage requirement as modified with accommodations would substantially burden the exercise of religion. *Contra* ECF No. 51 at 26.

The agency Defendants here once asserted that the "accommodation furthers the compelling interest in ensuring that women covered by every type of health plan receive full and equal health coverage, including contraceptive coverage. At the same time, it goes to great lengths to separate objecting employers from the provision of contraceptive coverage and to minimize any burden on religious exercise." *Zubik*, Case No. 14-1418, 2016 WL 1445915 (U.S. April 12, 2016) (Supp. Brief). As of April 2016, "[r]eligious organizations providing coverage to hundreds of thousands of people have now invoked the accommodation to opt out of the contraceptive-coverage requirement." *Id.* Only a year later, these same agencies now abandon the compelling interest in ensuring that those hundreds of thousands of people receive equal access to health care. ECF No. 51 at 26.

Defendants attempt to justify their decision under RFRA, in part, by minimizing the interest of providing contraceptive coverage. Birth control, they have decided, is just not that important after all. ECF No. 51 at 26-27. They assert that this is a "technical judgment" within their expertise, and so the Court should not second-guess it. ECF No. 51 at 27. But this ignores that Defendants deferred such technical judgment first to the Institute of Medicine (IOM) to determine what services to cover, and the IOM found—after exhaustive review of scientific evidence—that contraception *is* essential preventive medicine for women. *See* ECF No. 24 at 7-8. Later, in December 2016, as the federal government sought to update the women's preventive guidelines, it deferred this technical judgment to the American Congress of Obstetricians and Gynecologists (ACOG). ACOG likewise determined that contraception is essential preventive care for women. *See* ECF No. 24 at 10. Defendants fail to adequately justify a complete about-face in abandoning their former compelling interest in public health and women's preventive care and screenings, including contraceptive coverage as an essential women's health benefit.

Defendants attempt to justify their new position by relying on the exclusion of grandfathered plans and the previously available exemption and accommodation. ECF No. 51 at 26-27. These excuses minimize the importance not just of birth control, but of resolving compelling interests. The IFRs fail to reconcile, as RFRA itself requires, the federal law's guarantee of women's access to contraceptive services and religious interests.

3. The IFRs Were Improperly Issued Without Notice and Comment

a. Defendants Have Not Shown that Good Cause Excused Their Compliance with Notice and Comment Procedures

Defendants wrongly contend that providing notice and comment would be "contrary to the public interest," and thus that they have established "good cause" for their failure to comply with the full procedural requirements of the ACA.[7] ECF No. 51 at 16; 5 U.S.C. § 553(b)(B). Defendants' stated purposes—the need to effectuate their desired policies more quickly and to end litigation and general uncertainty surrounding the contraceptive mandate—fail to satisfy the high bar for an agency's burden to show that providing notice and comment would be contrary to the public interest.[8] See *San Diego Air Sports Ctr., Inc. v. FAA*, 887 F.2d 966, 969 (9th Cir. 1989) (good cause exception "must be narrowly construed and only reluctantly countenanced").

To determine whether Defendants have shown "good cause," the court must ascertain "not whether *dispensing* with notice and comment would be contrary to the public interest, but whether *providing* notice and comment would be contrary to the public interest." *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012) (italics original). Providing notice may be contrary to the public interest where, for example, "announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent." *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2001); *see also United States v. Valverde*, 628 F.3d 1159, 1165-1168 (9th Cir. 2010) (rejecting "contrary to public interest" justification).

Defendants' desire for expediency and their interest in reducing uncertainty and litigation are factors that are present in nearly every agency rulemaking.[9] Were these factors sufficient to

[7] The IFRs stated that "good cause" was supported both by the "impracticability" and "public interest" exceptions, although Defendants argue only the latter exception in their opposition brief. *See* ECF No. 51 at 16-18. Defendants have never argued that providing notice and comment was "unnecessary."

[8] Defendants also argue that failing to comply with notice and comment is justified because of the interim nature of the rule, the availability of post-promulgation public comment, and the fact that it received comments on related issues in the past. ECF No. 51 at 16-18. But these arguments do not speak to whether providing notice and comment would be contrary to the public interest, and are more properly addressed in the harmless error analysis. *See infra* at 9-10.

[9] Given that the prior regulations generated over 400,000 comments, ECF No. 51 at 5, indicating a strong public interest in contraception coverage, it was particularly important to allow notice and comment here.

support good cause, the requirement of notice and comment would be obsolete. *See Valverde*, 628 F.3d at 1166 (if interest in eliminating uncertainty constituted "good cause," the exception "would swallow the rule"); *United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009). And these justifications do not show that this is the "rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest." *Mack Trucks*, 682 F.3d at 95. Thus, the IFRs are procedurally defective and legally invalid. *See Linoz v. Heckler*, 800 F.2d 871, 878 (9th Cir. 1986).

b. The Error Was Not Harmless Because It Directly Affected the Procedure

It is "antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later." *Paulsen v. Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005). Courts must "'exercise great caution'" in applying the harmless error rule in the APA context. *Id.* at 1006. Failure to provide notice and comment is harmless only where the "'agency's mistake clearly had no bearing on the *procedure used* or the substance of decision reached.'"[10] *Id.* (emphasis added); *see also Buschmann v. Schweiker*, 676 F.2d 352, 358 (9th Cir. 1982) (error not harmless even where agency subsequently promulgated valid rule with identical language).

Much like their arguments in support of "good cause," Defendants' proffered reasons for why failure to provide notice and comment was harmless error—post-promulgation public comment, the interim nature of the rule, and prior opportunities to comment on rules relating to the same general subject matter—are present in nearly every issuance of an IFR. ECF No. 51 at 18. Notice and comment procedures may not be so easily evaded. Indeed, the Ninth Circuit held that failure to provide notice and comment was not harmless under very similar circumstances. *See Paulsen*, 413 F.3d at 1006-08 (error not harmless despite interim nature of rule, post-

[10] Defendants cite *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009) for the proposition that a plaintiff bears the burden of demonstrating that the error was harmless. ECF No. 51 at 18. But *Sanders* held no such thing. *Sanders* interpreted a harmless error statute specific to agency adjudication of veteran disability claims. *Sanders*, 556 U.S. at 406. Its analysis did not extend to harmless error analysis in the agency rulemaking context. Moreover, the Court held that harmless error should generally be determined based on a "case-specific application of judgment" and "examination of the record," not "through the use of mandatory presumptions and rigid rules." *Id.* at 407. *Sanders* is accordingly inapposite.

promulgation comment, and public comment on prior rule relating to same issue).[11] Defendants' failure to observe notice and comment procedures denied the States meaningful opportunity to offer comments before the IFRs were enacted, and the States' comments submitted to these IFRs, already in effect, do not suffice.[12] This error cannot be harmless because it is not "clear" that the error "had no bearing on the procedure used." *Id.* at 1006.

c. Congress Has Not Expressed a "Clear Intent" that Notice and Comment Procedures "Need Not Be Followed"

Defendants argue that they are statutorily empowered to issue regulations relating to health plans without observing notice and comment procedures. Congress may exempt certain rulemakings from compliance with notice and comment procedures, but only when it "sets forth specific procedures that 'express[ ] its clear intent that APA notice and comment procedures need not be followed.'" *Asiana Airlines v. F.A.A.*, 134 F.3d 393, 398 (D.C. Cir. 1998); 5 U.S.C. § 559. Congress indicates an intent to supplant notice and comment procedures when a statute directs that the agency "shall" issue an IFR, specifically identifies the subject matter of the exempt regulation, and establishes deadlines that could generally not be met were notice and comment procedures followed. *See Asiana Airlines*, 134 F.3d at 395; *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1236 n.18 (D.C. Cir. 1994). The statutes at issue here do none of these things. Their language merely confirms the agencies' existing powers under the APA. 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92 (agency "may promulgate" IFRs as agency determines "appropriate"). Under Defendants' reading, these statutes would confer broad power to jettison notice and comment procedures whenever they so desire. But if Congress intended such an extraordinary result, it surely would have said so clearly. The only court to consider the issue reached precisely this conclusion when it rejected the notion that 42 U.S.C. § 300gg-92

[11] The cases cited by Defendants holding that the error was harmless are distinguishable. ECF No. 51 at 18. Unlike those cases, here the public received no notice that "enabled [it] to participate in the rulemaking process before" the rule was adopted. *Paulsen*, 413 F.3d at 1007 (distinguishing *Idaho Farm Bureau*, *Riverbend*, and *Sagebrush Rebellion*).

[12] Given that the HHS has already issued guidance on how to implement the IFRs, it does not appear that the Defendants expect public comment to inform implementation. Memorandum from Randy Pate, Director, Center for Consumer Information and Insurance Oversight, November 30, 2017 (https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf) (CMS Memo).

conferred such broad discretionary authority. *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 17-19 (D.D.C. 2010). There is no reason for this Court to arrive at a different result.

4. The IFRs Are Arbitrary and Capricious Because Defendants Failed to Provide an Adequate Justification for Changing Its Position

When the government enacts a change in policy through regulation, it must acknowledge and explain its changing position. *FCC v. Fox Television Stations, Inc*., 556 U.S. 502, 515 (2009); *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d at 1112, 1119 (D.C. Cir. 2010). The IFRs allowed a new broad class of employers, insurers, and individuals to evade the ACA's contraception coverage requirement. Whereas previously, contraception was among the suite of required preventive services, subject to narrowly-tailored exemptions and accommodations, under the IFRs contraception is the sole preventive health benefit that an insurer or employer may simply decide to exclude—thereby transmuting contraceptive coverage from a requirement into an option. The federal government fails to provide adequate justification and cannot gloss over the 62 million women who have relied on access to no-cost birth control for preventive health care since the ACA was enacted. ECF No. 24 at 13; *see FCC*, 556 U.S. at 515 ("detailed justification" is necessary where there are "serious reliance issues" at stake). The IFRs constitute arbitrary and capricious rulemaking where medical science—which indicates that women and children have better health outcomes because of the ability to plan pregnancies—has not changed since the original accommodation process. Finer Decl. ¶ 43.

Defendants rely on the President's Executive Order directing them to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4)." ECF No. 51 at 23; *see* ECF No. 24-1 at 2. But the President cannot order Defendants to ignore the Congressional mandate that Defendants "shall provide" women's preventive care. 42 U.S.C. § 300gg-13(a)(4).

Defendants claim that these regulations are simply the last step in its attempts to accommodate religious objections. ECF No. 51 at 1, 7. While this narrative might be a facile way to downplay the impact of Defendants' regulatory action, it leaves them ill-equipped to meet the requirement of acknowledging and explaining their change in position. Defendants side-step

their responsibility to acknowledge or explain the significant change in policy by accusing the States of attempting to subject them to a "more searching standard of review." ECF No. 51 at 22. But the requirement to recognize the nature of their action—and its impact on millions of women—is not a standard of review. Rather, the APA requires that analysis which is entirely lacking in the IFRs. Defendants embrace that omission by minimizing the impact of the IFRs, stating that the accommodations are still available and that the exemptions are "cabined to those with sincere religious and moral beliefs." ECF No. 51 at 24. But there is no "cabining" such exemptions in practice. Rather, the IFRs make the accommodations process "optional" and "voluntary." ECF No. 24-1 at 1; ECR No. 24-2 at 1.[13]

C. The States' Constitutional Claims Are Likely to Succeed

1. The States Have Standing to Bring Constitutional Claims

Defendants argue that the States lack standing because they have purportedly failed to show any injury. To demonstrate an "injury in fact," the States must show (1) an invasion of a legally protected interest (2) that is concrete and particularized, and (3) harm that is actual or imminent, not conjectural or hypothetical. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016). Here, the States have standing based primarily on the fiscal harm the IFRs cause.[14] *Clinton v. New York*, 524 U.S. 417, 432-33 (1998) (New York had standing to contest veto of legislation to permit the state to keep disputed Medicaid funds); *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel. Barez*, 458 U.S. 592, 601-602 (1982) (state can assert standing based on its fiscal interests). Standing requires a litigant show only a minimal amount of financial harm, or predicted financial harm. *Council of Ins. Agents & Brokers v. Molasky-Arman*, 522 F.3d 925, 932 (9th Cir. 2008)

[13] The Centers for Medicare & Medicaid Services' guidance on implementing the IFRs provide that an employer or insurer could notify an insured who will no longer receive contraceptive coverage the same way it would notify the policyholder of any other change in benefits, through the Summary of Benefits of Coverage. CMS Memo, *supra* n. 11 at 3.

[14] Defendants erroneously suggest that the States have attempted to establish standing through their *parens patriae* interest. ECF No. 51 at 10-11. Not so. The States allege that they will suffer direct harm, and that they are suing to protect their sovereign, quasi-sovereign, and proprietary interests. ECF No. 24 at ¶ 14. And contrary to Defendants' claim that Virginia has not adequately pled that it is has proprietary interest through its state-funded hospitals, ECF No. 51 at 11, n.12, the amended complaint explicitly states that these hospitals are "state providers." ECF No. 24 at ¶ 93.

(monetary loss need only be an "identifiable trifle") (quoting *United States v. Students Challenging Regulatory Agency Procedures,* 412 U.S. 669, 690 (1973)); *Mass. v. EPA*, 549 U.S. 497, 521-26 (2007) (Massachusetts had standing to petition EPA to regulate greenhouse gas emissions based on predicted financial losses caused by failure to reduce global warming).

As detailed in the States' opening brief, *see* ECF No. 28 at 29-32, the States will be injured by the IFRs in at least two ways. First, the States will bear increased costs of providing contraceptive services to eligible residents who lose coverage. Finer Decl. ¶¶ 58-59 (California), 66-67 (Delaware), 74-75 (Maryland), 82-83 (New York), 90-91 (Virginia); Whorley Decl. ¶ 10, 11; Cantwell Decl. ¶ 17; Tosh Decl. ¶ 34; Nelson Decl. ¶ 15; Rattay Decl. ¶ 7. This is especially true in Virginia, where there is no contraceptive equity law requiring insurance plans cover contraception. Whorley Decl. ¶ 8. There is no question that this harm is real; Defendants admit in the IFRs that as many as 120,000 women who need contraceptive coverage will lose it. ECF Nos. 24-1 at 24-33, 24-2 at 19-21. Of this number, more than one in five are residents of the States. *See* 2010 Census Briefs, *Age and Sex Composition: 2010*, at 4, 7 (issued May 2011), *available at* https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf. Given that the numerous employers involved in the *Zubik* litigation are likely to avail themselves of the new exemption, rather than the accommodation, Defendants appear to have significantly underestimated the impact of the IFRs on women and the States. *See also* Decl. of Sharita Gruberg, Ex. A (partial records obtained from federal government show that at least four large employers with employees in the States requested an accommodation between January 2014 and March 2016).

Defendants allege that this harm is self-inflicted, ECF No. 51 at 10, yet later acknowledge that in the absence of the IFRs "numerous other governmental programs" will "assist low-income women to access free or subsidized contraception." ECF No. 51 at 23. Indeed, the IFRs explicitly rely on the "multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women" to fill the coverage gap created by the undoing of the no-cost guarantee by the IFRs. ECF No. 1-1 at 42. Defendants also stated in their brief in *Zubik* that if a small employer elects not to provide coverage, "employees will ordinarily obtain coverage

through . . . [options including] Medicaid or another government program." *Zubik*, No. 14-1418, Brief of Respondents, 2016 WL 537623 (U.S. Feb. 10, 2016) at 65. In any event, leaving women without any public assistance to obtain contraception would rob Peter to pay Paul; the States would not reap any financial benefit because they would bear responsibility for covering the costs associated with the even greater rise in unintended pregnancies that would result.

Second, women who lose no-cost contraceptive coverage are more likely to become pregnant, and the States will suffer financial harm as a result of these unintended and often high-risk pregnancies. Finer Decl. ¶¶ 28, 38-43; Decl. of Hal Lawrence [Lawrence Decl.] ¶ 9; Decl. of Dan Grossman ¶¶ 8-9, Decl. of Lisa Ikemoto ¶ 5; Decl. of Dave Jones [Jones Decl.] ¶ 15; Tosh Decl. ¶ 35; Nelson Decl. ¶ 30; Rattay Decl. ¶¶ 6, 8; Decl. of Ruth Lytle-Barnaby ¶ 28. Whether these pregnancies end in miscarriage or abortion, or result in live birth, the States will share the cost of funding these medical procedures, both during and after pregnancy, as well as the long-term costs of social services. Finer ¶¶ 54, 61 (California), 69 (Delaware), 77 (Maryland), 85 (New York), 93 (Virginia); Tosh Decl. ¶¶ 26-28; Rattay Decl. ¶¶ 5, 8. This is particularly true because self-insured plans are not required to cover essential health benefits, including maternity care. *See* 29 U.S.C. § 1144(a), (b)(2)(A).

Defendants suggest that these "alleged harms rely on an attenuated chain of causation." ECF No. 51 at 10. But a causal chain "does not fail simply because it has several links." *Maya v. Centex Corp.*, 658 F.3d 1060, 1070 (9th Cir. 2011) (internal quotations omitted). Instead, "what matters is not the 'length of the chain of causation,' but rather the 'plausibility of the links that comprise the chain.'" *Nat'l Audobon Soc'y v. Davis*, 307 F.3d 835, 849 (9th Cir. 2002) (quoting *Autolog Corp. v. Regan*, 731 F.2d 25, 31 (D.C.Cir.1984)). None of the links in the chain here is "hypothetical" or "tenuous"; the declarations that accompany this motion—from respected researchers and public servants—show that the IFRs will block women from receiving contraceptive services, that unintended pregnancies will result from the lack of contraceptive access, and that these pregnancies will impose a financial burden on the States. In short, the financial harm borne by the States is an "injury in fact" sufficient to bring constitutional claims.

2. The IFRs Violate the Establishment Clause

The IFRs violate the Establishment Clause because they impose religious beliefs on third parties. Defendants point out that the government must sometimes accommodate the exercise of religion, and "there is room for play in the joints" between the Free Exercise Clause and the Establishment Clause. ECF No. 51 at 30 (quoting *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005)). While there may be "play in the joints" between the competing interests of allowing the free exercise of religion and avoiding government favoritism toward religion, "[a]t some point, accommodation may devolve into 'an unlawful fostering of religion.'" *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 334–35 (1987) (quoting *Hobbie v. Unemployment Appeals Comm'n of Fla.*, 480 U.S. 136 (1987)). This is that case. While the prior regulations' accommodation and exemption were narrowly-tailored to allow for exercise of religious freedoms and still provide essential women's preventive care, the IFRs go needlessly far toward endorsing religion.

The IFRs cannot pass the three-pronged test under *Lemon v. Kurtzman*, 403 U.S. 602 (1971). A failure of any one of these parts is sufficient to invalidate the IFRs under the Establishment Clause. First, the IFRs do not have a secular purpose. Defendants contend that the IFRs alleviate governmental interference with religion. ECF No. 51 at 30-31. But this is not the case; the ACA is, on its face, entirely religion-neutral. The previous structure of accommodations and exemptions was narrowly tailored to allow for the practice of religion and still provide contraceptive coverage. Here, Defendants have jettisoned this dual purpose and fashioned a regulation solely to favor religion. Defendants concede they crafted the IFRs in response to Executive Order 13,798, which was directed at religion. ECF No. 51 at 7. And Defendants cannot salvage the Religious IFR by including the Moral IFR; laws that privilege religious institutions are invalid, even if they extend that privilege to non-religious institutions. *See Larkin v. Grendel's Den*, 459 U.S. 116 (1982) (zoning law violates Establishment Clause when it allows either churches or schools to veto liquor licenses to nearby businesses).

Second, the primary effect of the IFRs is to advance religion because it forces women employees to bear the burden of their employers' belief. Defendants contend that the IFRs

remove a burden on religious employers, but the exemption and accommodation already removed that burden. Rather, Defendants placed the burden on employees. Defendants blithely maintain that employees are not burdened by their employer's religious beliefs because "[n]othing in the rule obligates women working for objecting employers to change their beliefs about contraceptives." ECF No. 51 at 28. Of course, this avoids the issue. The female employees bear the burden of their objecting employers' religious beliefs because they lose their contraceptive coverage, thereby forcing them to seek other employment; obtain birth control at their own expense or the States' expense; or forgo birth control altogether.

This third-party burden is exactly what the Establishment Clause prohibits under *Estate of Thornton v. Caldor*, 472 U.S. 703 (1985). There, the Court held that a statute requiring employers to allow employees time off to observe religious holidays violated the Establishment Clause because it forced employers and fellow employees to shoulder the burden of the religious employee's faith: "The State has thus decreed that those who observe a Sabbath any day of the week as a matter of religious conviction must be relieved of the duty to work on that day, no matter what burden or inconvenience this imposes on the employer or fellow workers." *Id*. at 708-09. Notably, the court stated that the statute could have been narrowed and tailored to mitigate that burden, by allowing exceptions or reasonable accommodations, and thus resolved the constitutional violation. *Id*. at 709-10. But because the statute made no attempt to relieve the burden of the religious observance from the third parties, the Court found that it "goes beyond having an incidental or remote effect of advancing religion. The statute has a primary effect that impermissibly advances a particular religious practice." *Id*. at 710 (citations omitted). The same is true here, and Defendants make little argument to the contrary.

Third, the IFRs excessively entangle the government with the religious interests that object to contraceptive coverage. Among other things, Congress enacted the ACA to ensure access to essential preventive health care and to improve equality in health care for women. The IFRs undermine the reforms enacted by the ACA to empower patients to make decisions about their own healthcare, and instead put employers' religious interests in the position of determining whether an employee may receive birth control coverage without cost-sharing.

3. The IFRs Violate the Equal Protection Clause

The IFRs violate the Equal Protection Clause because Defendants fail to demonstrate an "exceedingly persuasive justification" for the IFRs, which draw a gender classification. *United States v. Virginia*, 518 U.S. 515, 531 (1996). Defendants claim that the IFRs do not discriminate based on sex by pointing to the fact that male contraceptives are not required at all under the ACA. ECF No. 51 at 33. In fact, this simply proves the point, because contraceptives are required under the ACA as preventive health care for *women*. Only women get pregnant. So the gender classification is whether contraceptives, as an essential element of women's preventive care, are treated similarly to men's preventive care—and they are not.

No exceedingly persuasive justification supports this gender classification, which is directly contrary to the ACA's intent to eliminate gender disparities in health care. Defendants summarily restate their conclusion that the Religious IFR is required to accommodate religious interests, ECF No. 51. at 34, but such a broad exemption is unwarranted. *See supra* 6-7. Defendants' sole support for the Moral IFR is that it is consistent with other conscience provisions that did not involve constitutional claims. In fact, although Defendants reject any intent to discriminate, ECF No. 51 at 34, they are openly dismissive of the need for contraceptive coverage; they plainly state that—despite the IOM and ACOG reports finding contraceptive care to be basic preventive care for women—"the effect of contraceptives and broad coverage mandates on women's health . . . [were] not adequate to establish a compelling interest." ECF No. 51 at 27.

II. THE IFRS INFLICT IRREPARABLE HARM UPON THE STATES

The States will suffer irreparable harm in at least three ways. First, as Defendants admit, irreparable harm exists if one or both of the States' constitutional claims are likely to succeed on the merits. ECF No. 51 at 13. Second, the APA violations here, particularly the deprivation of a meaningful public comment period before the IFRs became effective, will cause harm that cannot be undone, given the "far-reaching changes that will likely have significant effects" on the States. *See Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17, 18 (D.D.C. 2009). And third, the States will be burdened not only with providing contraceptive coverage to those who lose it, but with the irreversible consequences of an upswing in unintended pregnancies—short-

term medical costs associated with the pregnancies and their aftermath and long-term costs from the inability of affected women to contribute to the States as students, researchers, workers, and taxpayers. Finer Decl. ¶¶ 45, 54, 61, 69, 77, 85, 93; Tosh Decl. ¶¶ 26-28, Rattay Decl. ¶¶ 5, 8; Lawrence Decl. ¶ 5; Arensmeyer Decl. ¶ 4; Nelson Decl. ¶ 31, Decl. of Keisha Bates ¶¶ 3, 6.

Defendants suggest that the States have not shown that these harms are imminent and concrete.[15] ECF No. 51 at 14. Yet the IFRs took effect immediately on October 6, 2017, allowing employers not covered by contraceptive equity laws to exempt themselves from the no-cost contraceptive coverage requirement at any time after providing sufficient notice to affected employees. ECF Nos. 24-1 at 2, 24-2 at 1. Given that the IFRs eliminate the requirement for employers to disclose their exempt status to the government, the scope of the harm to women and the States is, by design, not easily quantified. But no matter the "magnitude of the injury," *see Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 724 (9th Cir. 1999), some number of women have already lost coverage or will soon lose coverage, and the States will suffer irreparable harm as a result. ECF Nos. 24-1 at 24-33, 24-2 at 19-21; *see also* Jones Decl. ¶¶ 23-24.

III. ISSUING AN INJUNCTION TO PRESERVE THE STATUS QUO WOULD PROPERLY BALANCE THE EQUITIES AND SERVE THE PUBLIC INTEREST

While prior ACA regulations struck a delicate balance that both accommodated sincere religious beliefs and ensured full and equal health coverage for women—and the Supreme Court endorsed this aim, *Zubik*, 136 S. Ct. at 1560—the IFRs attempt no such compromise, but instead favor the former values to the exclusion of the latter. Returning the parties to the status quo that existed before the IFRs would properly balance the equities and serve the public interest by ensuring that the significant public health benefits of contraception are more widely available to women. *Chalk v. U.S. Dist. Court Cent. Dist. Cal.*, 840 F.2d 701, 704 (9th Cir. 1988) (purpose of injunction is to preserve the status quo).

CONCLUSION

The States request that the Court grant this motion for preliminary injunction.

[15] While Defendants rushed the IFRs into effect without notice and comment to provide immediate relief to religious and moral objectors, they now assert a lack of imminent harm.

Dated: December 6, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

Case Name: ***St. of Ca. et. al v. Health & Human Services, et al.*** **No: 4:17-cv-05783-HSG**

I hereby certify that on December 6, 2017, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

States' Reply in Support of Motion for Preliminary Injunction

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on December 6, 2017, at Sacramento, California.

Francina M. Stevenson	*/s/ Francina M. Stevenson*
Declarant	Signature

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